



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : Jackowski et al.
Serial No. : 09/846,328
Filed : April 30, 2001
For : **Biopolymer Marker Indicative
of Disease State Having A
Molecular Weight of 2753
Daltons**
Examiner : Cheyne Dune Ly
Art Unit : 1631
Our File No. : 2132.051

CERTIFICATE UNDER 37 CFR 1.8(a)

I hereby certify that this correspondence is being
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Susan Idess

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DECLARATION UNDER 37 CFR § 1.132

I, Ferris H. Lander, do hereby declare as follows:

1. I am a registered Patent Agent and am authorized to represent the inventor's and assignee in the application entitled "**Biopolymer Marker Indicative of Disease State Having A Molecular Weight of 2753 Daltons**", having U.S. Application Serial No. 09/846,328, filed April 30, 2001.

2. In the Office Action mailed on March 11, 2003, claims 1 and 2 were rejected under 35 U.S.C. 101 because the claimed invention allegedly lacks patentable utility due to its not

being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility. The Examiner states at page 5 of the Office Action that the disclosure is not substantial because the specification lacks a description of negative controls in order to establish the specificity of the claimed biopolymer marker. At page 6 of the Office Action, the Examiner questions how the marker can be used to indicate disease states without the disclosure necessary for distinguishing individuals inflicted with a specific disease state versus individuals not inflicted with the specific disease.

3. In order to provide data which would obviate this rejection, I contacted Dr. George Jackowski, Chairman and Chief Science Officer of Syn-x Pharma Inc., and asked to be provided with evidence of the absence of the 2753 dalton marker in normal human sera.

4. This declaration (including the attached figure) is provided in order to show a comparison of the serum profile of individuals having insulin resistance to the serum profile of non-diseased individuals, so as to evidence that the marker (the 2753 dalton peptide) was not present in normal human sera.

The attached figure, obtained from Dr. Jackowski, provides side-by-side profiles (obtained using techniques of mass spectrometry) of normal human sera versus sera from patients having insulin resistance. This profile comparison clearly

evidences the absence of the 2753 dalton marker in normal human sera.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

6/9/2003
Date

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